



CDER Export Compliance

Presented by

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Exports: 1906

Drugs compliant with the Federal Food Drug and Cosmetic Act (the Act or FFDCA)

- No export restrictions

Drugs which are non-compliant with the Act

- It is prohibited to introduce an adulterated or misbranded drug into interstate commerce
- Criminal and Civil Penalties
- When intended for export the drug is not misbranded or adulterated if
 - prepared/packed to specifications/directions of the foreign purchaser
 - substances not conflict with the laws of the foreign country
 - Drug is not offered for sale in the United States

Exports

1938

Defined “drug” and “new drug” and codified 1906 into FFDCA 801(d), [21 USC 381(d)], may not export new drugs

1986

Free markets and the start of globalization leads to reduced regulation through export applications:

- Export to the “First World” (Modernized Europe, Japan, Australia & New Zealand); or
- Drugs to treat tropical diseases; or
- Partially processed biologics

Export Globalization 1996

Market Globalization takes effect with “FDA Export Reform and Enhancement Act (EREA)”

- No need for FDA export applications or prior export approval; instead created a simple notification process
- Export unapproved drugs to virtually anywhere
- Export unapproved drugs and biologicals intended for investigational use to listed countries
- May apply to export unapproved drugs intended to treat diseases of very low prevalence in U.S.

Current Exports

Misbranded or adulterated drug which do not require an approved New Drug Application

- FFDCA 801(e), (f) [21 USC 381(e), (f)]

Unapproved New Drug

(subject to FFDCA 505, OTC monograph or licensing)

- FFDCA 802 and 801(e)(1) or
- 21 CFR 312.110(b) the IND Exports Regulations

Exports Requirements

- FFDCA 801(e)(1) A drug intended for export shall not be deemed adulterated or misbranded under this Act if it--
- (A) accords to the specifications of the foreign purchaser
 - (B) is not in conflict with laws of the country to which it is intended for export
 - (C) is labeled on the outside of the shipping package that it is intended for export, and
 - (D) is not sold or offered for sale in domestic commerce

Intended to allow drug to be introduced into interstate commerce (export) without violating FFDCA 301(a)

Additional Export Labels

801(f) Labeling of exported misbranded or adulterated drugs with additional label requirements:

- Both the FDA and the required foreign labeling must be on/with the product
- Must declare any indications which diverge from the FDA approval are not FDA unapproved indications for use

Exports 802

- Unapproved new human drugs can be exported when:
 - It complies with the laws of the importing country and
 - It has marketing authorization in Australia, Canada, Israel, Japan, New Zealand, South Africa, or a country in the European Union, European Free Trade Association, or authorized to be marketed in the European Economic Area
- Approved human drugs exported for unapproved uses
 - Investigational use in listed country (see above)
 - Further processing with a pending market authorization (licensing, listing)
- Provision to allow shipping of drugs for tropical diseases or not of significant prevalence in the U.S.

Exports 802

- 801(e)(1)?
- GMPs?
- Filthy?
- Putrid?
- Injurious to health?
- Strength, purity and quality?
- Imminent domestic public health hazard?
- Imminent foreign public health hazard?

Export Notification

FFDCA 802(g) and 21 CFR 1.101(d)

- Notification not needed under 801
- Simple Export Notification under 802
 - Provide initial notification identifying the drug and the country to which the drug is being exported
 - Unapproved export notifications to CDER OC
 - Export Notification for INDs go to the Office of International Programs

Exports Records

When an unapproved new drug is *first* exported, the exporter must maintain records including:

- Drug trade name, abbreviated or proper name
- Strength and dosage form
- Name of importing country
- Drug lot or control number
- Consignee name and address
- Date product was exported
- Quantity of drug exported
- Product meets foreign purchaser specifications
- Product does not conflict with laws of importing country
- Shipping label of exported product states for export only
- Documentation that product is not sold/offered for sale in U.S.

Export Mission Impossible?

Exporting to an unlisted country and no marketing authorization:

- The drug must comply with importing country's laws &
- The FDA must determine those laws are appropriate

OR

- Petition FDA with an specific drug application including “credible scientific evidence” acceptable to U.S. and the importing country's authority

Exports and OC

Compliance Role

- Provide assistance to the FDA field
- Receive export notifications
- Review Drug Exporter Inspections
- Issue Warning Letters
- Review consent decrees
- Process export certificate (CPP) requests
- Process export applications
 - Requests under 802(b)(2)
- Handle PEPFAR requests



Certificate of a Pharmaceutical Product* (CPP) Application Process

Presented by

Betty McRoy

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*The following presentation pertains to the Center for Drug Evaluation and Research issued export Certificates of Pharmaceutical Product (CPP)

What is a CPP?

- Certificate for human drug products, including human biologics, which conform to the World Health Organization's certification requirements.

(CPG 7150.01)

- The CPP also contains information about the pharmaceutical regulatory or marketing status in the US.

Certificates May Be Issued

- Drugs that are legally marketable in the U.S.
- Drugs not authorized for sale in the U.S. which may be legally exported to a foreign country
- For a foreign manufactured drug (i.e. made outside the U.S.)

Types of Drugs for which CPPs may be Issued

1. Approved drug products
2. Over the counter drug (OTC) products
3. Unapproved drug products
4. Homeopathic drugs
5. Active pharmaceutical ingredients (API) or bulk drug substances

Who can apply for CPP?

- Anyone who exports a drug may submit a complete application for export certification
- The certification is intended for a drug which either:
 - meets the requirements of 801(e)(1) of the Food Drug and Cosmetic Act [21 U.S.C. 381(e)(1)] or
 - meets the applicable requirements of the Act

Process to apply for a CPP

- Submit Form 3613b
 - Located on the FDA internet
 - <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM052388.pdf>

Required CPP Application Information

- Applicant Contact Information
- U.S. Tradename (the drug product's brand name)
- Bulk Substance Generic Name
- Name of Applicant
- Status of Product License holder
- Complete Manufacturing Facility Address
- Facility Registration Number
- Listing of manufacturing location on CPP
- Importing countries
- Number of certificates requested
- Certification Statement
- Authorization to Release Information
- Billing contact
- Marketing Status in the Exporting Country (U.S.)

Additional Required Information

- **Foreign Manufactured Drugs**
 - Certification of Exportation from the U.S. for Foreign Manufacturing Sites
- **Approved Drug Products**
 - NDA, ANDA, AADA, BLA or Approval Letter
 - Outer Container Label(s)
 - Package Container (Immediate)
 - Package Insert
 - Status of Product-license Holder
- **Unapproved Drug Products**
 - Product Identification Statement
 - Formulation page
- **Over-the-Counter (OTC) Drug Products**
 - Title of the applicable monograph
 - Product Label(s)
 - Immediate Package Container Label
- **Active Pharmaceutical Ingredients (API)**
 - original sample of the current bulk container label
- **For Export Only**
 - Formulation page

Attachments to CPP

- An application for one country requires two sets of attachments (one set to attach to the certificate package and one set for FDA files).
- Attachments to the CPP must not exceed five pages per certificate.
- Applicant is responsible for consulting with the importing country to determine what type of information is required on the certificate.

Process Time

- Certificates for drugs in compliance are normally issued within twenty (20) government working days of receipt of an accurate and complete CPP application.
- Certificates may not be issued
 - Returned – if the application is missing information with a letter identifying the missing information.
 - Rejected – if the manufacturing facilities is not in compliance with good manufacturing practices (GMPs).
 - Denied – if the drug products are not in compliance with the regulation (e.g., misbranded drug)

Ribbons on CPPs

- Colored ribbons designate the type of CPP
 - **Red** for approved drug product, API, OTC marketed per monograph, and export only drugs.
 - **Blue** for unapproved drug product not marketed in the U.S.
 - **Yellow** for drug manufactured outside of the U.S.

CPP Fee Schedule

- First Certificate (original) - **\$175.00**
- Second Certificate - **\$90.00**
- Third and subsequent certificates - **\$40.00**

Expiration of CPP

- Certificates expire 24 months from the date of notarization or as noted.
- After expiration date, a new CPP application must be submitted.



Summary

- Obtaining a CPP
 - Know the requirements of the importing country prior to submitting an application
 - Complete application using Form 3613b
 - Ensure that you submit the required documentation
- Form 3613b includes instructions, please review the instructions before completing and submitting the application



Submit Export Certificate Questions

Via email to:

CDERExportCertificateProgram@FDA.hhs.gov

Via phone to:

301-796-4950